



Jessica Ryman-Rasmussen, PhD, DABT

Scientific Advisor

Regulatory and Scientific Affairs

1220 L Street, NW
Washington, DC 20005-4070
USA

Telephone 202-682-8473
Email rymanj@api.org

www.api.org

VIA Email

September 20, 2018

Mr. Thomas Carpenter
Sr. Biologist and Designated Federal Officer
U.S. EPA: Office of the Administrator, Science Advisory Staff Office
1200 Pennsylvania Ave, NW (1400R)
Washington, DC 20460-4164

RE: Notification of a Public Teleconference of the Chartered Scientific Advisory Board (SAB) [FRL-9983-39-OA]

Dear Mr. Carpenter:

The American Petroleum Institute (API) is pleased to submit written comments regarding the Public Teleconference of the Chartered Scientific Advisory Board (SAB) [FRL-9983-39-OA]. These comments pertain to the Advisory Activities Discussed of the IRIS Assessment for Ethyl Tertiary Butyl Ether (ETBE) and the IRIS Assessment for tert-Butyl Alcohol (tert-butanol) as well as the 08-30-2018 Draft Review of EPA's Draft Toxicological Review of Ethyl Tertiary Butyl Ether and Draft Toxicological Review of tert-Butyl Alcohol.

API is a national trade association that represents all facets of the oil and natural gas industry, with 625 plus members that include large integrated companies, as well as exploration and production, refining, marketing, pipeline and marine businesses, and service and supply firms. As a core component of our business model, we prioritize the promotion of public health and environmental safety while ensuring a strong, viable and sustainable U.S. oil and natural gas economy. Many API members are impacted by IRIS assessments. API advocates for risk assessment processes that use the best available science, are transparent, and provide opportunities for public engagement.

API is requesting that EPA's Science Advisory Board (SAB) Staff remedy the situation in which the SAB was unable to reach consensus on critical aspects of the IRIS assessments for ETBE and TBA by supporting a subsequent SAB that includes pathology expertise and/or supporting a recommendation that EPA/IRIS hold a transparent scientific workshop that includes expert pathologists in order to resolve these critical issues.

The rationale for this request is subsequently described and defended in detail.

In the 8-30-2018 SAB draft report¹ the SAB was unable to reach consensus on the human relevance of the kidney effects of ETBE and tBA as indicated by the following:

“Regarding noncancer kidney outcomes from exposure to ETBE, the SAB did not reach consensus on an oral reference dose. The difference in opinion is based on the extent of confidence in a CPN-based mechanism for these ETBE effects. Similarly, the SAB did not reach a consensus regarding the oral reference dose for noncancer kidney outcomes for tBA. The difference in opinion relates to the extent of confidence in CPN and/or alpha 2μ-globulin -based mechanisms for these tBA effects.”²

“A consensus was not reached for tBA concerning the scientific support for the conclusion that male rat kidney tumors are relevant to human hazard identification.”²

“No consensus, however, was reached regarding the EPA’s calculation of inhalation unit risk (IUR) for ETBE. Some members conclude that the data are not suitable for developing an IUR due to a potential lack of biological relevance for ETBE. Other members note that the data are appropriate for dose-response analysis for ETBE.”²

As a result, the IRIS Program is now in the very unfortunate position of not having consensus support from independent scientific peer review for key endpoints used in the ETBE and TBA assessments. Going forward, this can reasonably be anticipated to increase the level of difficulty for the IRIS Program in defending its risk assessments at a time in its history when it is already under a high level of scrutiny and pressure.

According to a 2002 document produced by the US EPA Science Advisory Board (SAB)³:

“The goal of the panel formation process is to assemble an appropriate panel of experts to provide sound, independent, balanced, and useful scientific and technical advice”

and

“Expertise, knowledge, and experience are primary factors that determine whether an individual is invited to serve on a SAB Panel.”⁴

¹ Review of EPA’s Draft Assessments titled Toxicological Review of Ethyl Tertiary Butyl Ether and Toxicological Review of *tert*-Butyl Alcohol (*tert*-Butanol). 8-30-2018.

² *Ibid.* Page 2.

³ Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board. EPA-SAB-EC-02-010. September 2002.

[https://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/\\$File/ec02010.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/$File/ec02010.pdf)

⁴ *Ibid.* Page 9.

API has previously noted in written comments⁵ that there was no apparent representation of expertise in pathology on this SAB and that this is also inconsistent with EPA's Peer Review Handbook.

API therefore requests the SAB Staff to remedy this situation in which the SAB was unable to reach consensus on critical aspects of these IRIS assessments by supporting a subsequent SAB that includes pathology expertise and/or supporting a recommendation that EPA/IRIS hold a transparent scientific workshop that includes expert pathologists in order to resolve these critical issues. API notes that if a scientific workshop were to be recommended, it could be expanded to include other substances that cause similar kidney effects in rodents, as these endpoints are applicable to substances other than ETBE and TBA.

Sincerely,

Jessica Ryman-Rasmussen, PhD, DABT

⁵ Written comments submitted by Jessica Ryman-Rasmussen on behalf of the American Petroleum Institute (API). [https://yosemite.epa.gov/sab/sabproduct.nsf/520B0D5561CA43668525825000637CE0/\\$File/API_Comments_ETBE-TBA_CAAC_03-13-2018_unsigned_final.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/520B0D5561CA43668525825000637CE0/$File/API_Comments_ETBE-TBA_CAAC_03-13-2018_unsigned_final.pdf)